

EXHIBIT B

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 21, 2021

INOTIV, INC.

(Exact name of registrant as specified in its charter)

Indiana	0-23357	35-1345024
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)
2701 KENT AVENUE WEST LAFAYETTE, INDIANA		47906-1382
(Address of principal executive offices)		(Zip Code)

Registrant's telephone number, including area code: (765) 463-4527

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act(17CFR240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act(17CFR240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act(17CFR240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Shares	NOTV	NASDAQ Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

☐

Item 7.01 Regulation FD Disclosure.

The Company is furnishing certain information regarding its business, some of which has not been previously reported, derived from the confidential preliminary offering memorandum that is being circulated in connection with the offering of the Notes described in Item 8.01. This information is included in Exhibit 99.5. This information shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

On September 21, 2021, Inotiv, Inc. (the “Company”) issued a press release relating to its proposed offering of Convertible Senior Notes due 2027 (the “Notes”) to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference into this Item 8.01.

Neither this Current Report on Form 8-K nor the press release constitutes an offer to sell, or the solicitation of an offer to buy, the Notes or the common shares of the Company, if any, issuable upon conversion of the Notes.

Item 9.01 Financial Statements and Exhibits.

(a) Financial Statements of Businesses or Funds Acquired.

1. Audited consolidated financial statements of Envigo RMS Holding Corp. as of December 31, 2020 and 2019 and for the year ended December 31, 2020 and the period from June 3, 2019 to December 31, 2019
2. Unaudited consolidated financial statements of Envigo RMS Holding Corp. as of and for the three and six months ended June 30, 2021 and 2020

(b) Pro Forma Financial Information.

1. Unaudited pro forma condensed combined financial statements of the Company, Envigo RMS Holding Corp., Bolder BioPath, Inc. and HistoTox Laboratories, Inc. is filed as Exhibit 99.1 to this Current Report on Form 8-K.
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(d) Exhibits

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The following exhibits are being filed as part of this report:

Exhibit No.	Description
99.1	Press release dated September 21, 2021
99.2	Audited consolidated financial statements of Envigo RMS Holding Corp. as of December 31, 2020 and 2019 and for the year ended December 31, 2020 and the period from June 3, 2019 to December 31, 2019
99.3	Unaudited consolidated financial statements of Envigo RMS Holding Corp. as of and for the three and six months ended June 30, 2021 and 2020
99.4	Unaudited pro forma condensed combined financial statements of the Company, Envigo RMS Holding Corp., Bolder BioPath, Inc. and HistoTox Laboratories, Inc.
99.5	Excerpts from Confidential Preliminary Offering Memorandum circulated in connection with Notes offering*
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

*Furnished, not filed.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Current Report on Form 8-K, including the exhibits hereto, contains forward-looking statements that involve risks and uncertainties. Those statements may include, but are not limited to, discussions regarding our intent, belief or current expectations with respect to (i) our strategic plans; (ii) trends in the demand for our products and services; (iii) trends in the industries that consume our products and services; (iv) our ability to develop new products and services; (v) our ability to make capital expenditures and finance operations; (vi) global economic conditions, especially as they impact our markets; (vii) our cash position; (viii) our ability to effectively integrate the operations and personnel related to recent acquisitions; (ix) our ability to effectively manage current expansion efforts in St. Louis, Missouri and any other future expansion or acquisition initiatives we undertake; (x) our ability to develop and build infrastructure and teams to manage growth and projects; (xi) our ability to continue to retain and hire key talent; (xii) our ability to market our services and products under our new corporate name and relevant brand names; (xiii) our ability to service our outstanding indebtedness; (xiv) our expectations regarding the volume of new bookings, pricing, gross margins and liquidity, (xv) the impact of COVID-19 on the economy, demand for our services and products and our operations, including measures taken by government authorities to address the pandemic, which may precipitate or exacerbate other risks and/or uncertainties, and (xvi) the Envigo Acquisition and its impact on our business, financial condition and results of operations.

All statements, other than statements of historical facts, are forward-looking statements. The words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “target,” “potential,” “will,” “would,” “could,” “should,” “continue,” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make.

Although we believe the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. You should not rely upon forward-looking statements as predictions of future events. Unless required by law, we will not undertake and we specifically disclaim any obligation to release publicly the result of any revisions which may be made to any forward-looking statements to reflect events or circumstances after the date of such statements or to reflect the occurrence of events, whether or not anticipated. In that

respect, we wish to caution readers not to place undue reliance on any such forward-looking statements, which speak only as of the date they are made.

This Report may include statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

INOTIV, INC.

Date: September 21, 2021

By: /s/ Beth A. Taylor
Chief Financial Officer,
Vice President—Finance

Risks Related to Regulation

Changes in government regulation or in practices relating to the pharmaceutical industry could change the demand for the services we provide.

Governmental agencies throughout the world, but particularly in the United States, strictly regulate the drug development process. Our business involves helping pharmaceutical and biotechnology companies comply with the regulatory drug approval process. Changes in regulation, such as a relaxation in regulatory requirements or the introduction of simplified drug approval procedures, or an increase in regulatory requirements that we may have difficulty satisfying, or that make our services less competitive, could substantially change the demand for our services. Also, if governments increase efforts to contain drug costs and pharmaceutical and biotechnology company profits from new drugs, our clients may spend less, or slow the pace of increased spending, on research and development.

Any failure by us to comply with existing regulations could harm our reputation and operating results.

Any failure on our part to comply with existing regulations could result in the termination of ongoing research or the disqualification of data for submission to regulatory authorities. For example, if we were to fail to properly monitor compliance with study protocols, the data collected could be disqualified. Under such circumstances, we may be contractually required to repeat a study at no further cost to the client, but at substantial cost to us. That development would harm our reputation, our prospects for future work and our operating results. Furthermore, the issuance of a notice from the FDA based on a finding of a material violation by us of good clinical practice, good laboratory practice or good manufacturing practice requirements could materially and adversely affect our business and financial performance.

Privacy regulations could increase our costs or limit our services.

U.S. Department of Health and Human Services regulations under the Health Insurance Portability and Accountability Act of 1996 demand compliance with patient privacy and confidentiality requirements. In addition, some state governments are considering more stringent regulations. The General Data Protection Regulation (GDPR), which became effective in May 2018, imposes heightened obligations on businesses that control and manage the personal data of E.U. citizens. These and similar regulations might require us to increase our investment in security or limit the services we offer. We could be found liable if we fail to meet existing or proposed regulations on privacy and security of health information.

Risks Related to Research and Development

Our future success depends on our ability to keep pace with rapid technological changes that could make our services and products less competitive or obsolete.

The biotechnology, pharmaceutical and medical device industries generally, and contract research services more specifically, are subject to increasingly rapid technological changes. Our competitors or others might develop technologies, services or products that are more effective or commercially attractive than our current or future technologies, services or products, or that render

future taxable income could cause the Company to pay U.S. federal income taxes earlier than it otherwise would if such limitations were not in effect and could cause certain of such NOLs to expire unused, thereby reducing or eliminating the benefit of such NOLs.

Risks Related to Envigo

Solely for purposes the disclosures below under this “—Risks Related to Envigo” caption, “we,” “our” and “us” refer to Envigo RMS Holding Corp.

Business and Operational Risk Factors

We depend on the biopharmaceutical industry.

Envigo’s business depends greatly on the expenditures made by the biopharmaceutical industry in research and development, either directly or indirectly via their outsourcing development to CROs. In recent years, over 20% of Envigo’s revenue has come from biopharmaceutical customers directly and 40% from CROs indirectly. Accordingly, economic factors and industry trends that affect our customers in these industries also affect our business. As well, if payers were to change their practices with respect to reimbursements for pharmaceutical products, our customers may spend less, or reduce their growth in spending on research and development.

Several of our product and service offerings are dependent on a limited source of supply, which, if interrupted, could adversely affect our business.

Envigo depends on a limited international source of supply for certain products, such as non-human primates, which we sometimes call “NHPs”. Disruptions to their continued supply may arise from health problems, export or import laws/restrictions or embargoes, international trade regulations, foreign government or economic instability, severe weather conditions, increased competition amongst suppliers for models, disruptions to the air travel system, commercial disputes, supplier insolvency, activist intervention, or other normal-course or unanticipated events. Any disruption of supply could harm our business if we cannot address the disruption or are unable to secure an alternative or secondary supply source on comparable commercial terms.

In December 2019, a novel strain of coronavirus (“COVID-19”) emerged in Wuhan, Hubei Province, China. We receive a portion of our NHPs from China. Due to restrictions enacted in China to mitigate the transmission of COVID-19, our supply of these NHPs was and continues to be disrupted. While we have been able to secure NHPs from other sources in Asia and Africa, the prolonged disruption has impacted our ability fill our customer’s orders. Envigo may be able to substitute another NHP, but not in all cases. This disruption has had an adverse effect on our financial results, which is expected to continue during 2021. We will continue to seek alternative NHP sourcing options to meet our customer’s needs.

Changes in aggregate spending, research and development budgets and outsourcing trends in the biopharmaceutical industry could adversely affect our operating results.

Our ability to continue to grow and win new business is dependent in large part upon the ability and willingness of the biopharmaceutical industry to continue to spend on compounds in the non-clinical phase of research and development. Fluctuations in the expenditure amounts in each phase

of the research and development budgets of these industries could have a significant effect on the demand for our products and services. R&D budgets fluctuate due to changes in available resources, mergers of biopharmaceutical companies, spending priorities, general economic conditions and budgetary policies. Our business could be adversely affected by any significant decrease in non-clinical research and development expenditures by biopharmaceutical companies.

Envigo operates in a highly competitive market.

The RMS industry is highly competitive. Competition ranges from academics and large biopharmaceutical companies, that derive and maintain their own rodent colonies, to commercial competitors that may offer a similar or overlapping range of products and/or services. Some of these competitors have greater capital, technical and other resources than we have, while other competitors that are smaller specialized companies might compete effectively against us based on price and their concentrated size and focus.

Providers of outsourced research models and services compete on the basis of many factors, including the following:

- reputation for on-time quality performance;
- reputation for regulatory compliance; expertise, experience and operational stability;
- quality of facilities;
- quality and stability of the animal models and laboratory animals;
- assurance of supply;
- technical and scientific support;
- strength in various geographic markets;
- geographic proximity to customer;
- price; and
- financial stability.

New technologies may be developed, validated and increasingly used in biomedical research that could reduce demand for some of our products and services.

For many years, groups within the scientific and research communities have attempted to develop models, methods and systems that would replace or supplement the use of living animals as test subjects in biomedical research. In addition, technological improvements to existing or new processes, such as imaging and biomarker technology, could result in a refinement in the number of animal research models necessary to conduct the required research. Alternative research methods could decrease the need for research models, and we may not be able to develop new products effectively or in a timely manner to replace any lost sales. In addition, other companies or entities may develop research models with characteristics different than the ones that we produce, and which may be viewed as more desirable by our customers.

It is industry policy to adopt and implement the 3R's of Replacement, Reduction and Refinement, which could decrease the number of animals used in biomedical research.

Legal and Regulatory Risk Factors

Failure to comply with applicable governmental regulations could harm our business.

Envigo is subject to a variety of governmental regulations, particularly in the United States, Europe, and the United Kingdom, relating to animal welfare and the conduct of our business, including the U.K. Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012 and U.S. USDA Animal Welfare Regulations. Our facilities are therefore subject to routine formal inspections by regulatory and supervisory authorities, including the U.S. FDA, the U.S. USDA and the U.K. Home Office, as well as by representatives from customer companies.

Envigo expends significant resources on compliance efforts. Regulations and guidance worldwide concerning the production and use of laboratory animals for research purposes continue to be updated. For example, the European Directive 2010/63/EU established new standards for animal housing and accommodations that required implementation by 2017; we previously incurred significant capital expenditure to comply with the Directive. Similarly, guidance has been and continues to be developed for other areas that impact the biomedical research community on both a national and international basis, including transportation, import and export requirements of biological materials, and animal housing and welfare. Certain of our customers may require us to comply with any new guidance in advance of our implementation as a condition to being awarded contracts. Conforming to new guidelines may result in increased costs attributable to adding or upgrading facilities, the addition of personnel to address new processes and increased administrative burden.

Envigo is subject to environmental, health and safety requirements and risks as a result of which we may incur significant costs, liabilities and obligations.

Envigo is subject to a variety of federal, state, local and foreign environmental laws, regulations, initiatives and permits that govern, among other things: the emission and discharge of materials, including greenhouse gases, in air, land and water; the remediation of soil, surface water and groundwater contamination; the generation, storage, handling, use, disposal and transportation of regulated materials and wastes, including biomedical and radioactive wastes; and health and safety. Failure to comply with these laws, regulations or permits could result in fines or sanctions, obligations to investigate or remediate existing or potential contamination, third-party property damage claims, personal injury claims, natural resource damages claims, or modification or revocation of operating permits and may lead to temporary or permanent business interruptions. Pursuant to certain environmental laws, we may be held strictly, and under certain circumstances jointly and severally liable for costs of investigation and remediation of contaminated sites which we currently own or operate, or sites we or our predecessors have owned or operated in the past. Further, we could be held liable at sites where we have sent waste for disposal.

Environmental laws, regulations and permits, and the enforcement thereof, change frequently and have tended to become more stringent over time. Compliance with the requirements of laws and regulations may increase capital costs and operating expenses, or necessitate changes to our production processes.

We endeavor to conduct our operations according to all legal requirements, but we may not be in complete compliance with such laws and regulations at all times. We use, and in the past have used, hazardous materials and generate, and in the past have generated, hazardous wastes. We cannot eliminate the risk of accidental contamination or injury from these materials. In the event of such an accident, we could be held liable for any resulting damages and incur liabilities which could exceed our resources. Our costs, liabilities and obligations relating to environmental matters may have a material adverse effect on our business, financial condition, prospects, results of operations and cash flows.

Envigo may not be able to successfully develop and market or acquire new products and services.

Envigo may seek to develop and market new products and services that complement or expand our existing business or expand our offerings through acquisition. If we are unable to develop new products and services and/or create demand for those newly developed products and services, or expand our offerings through acquisition, our future business, results of operations, prospects, financial condition, and cash flows could be adversely affected.

Labor and Employment Risk Factors

Envigo depends heavily on our senior management team, and the loss of any member may adversely affect us.

Envigo believes its success depends on the continued availability of our senior management team, including Dr. Adrian Hardy (CEO) and Stephen Symonds (CFO). If one or more members of the senior management team were unable or unwilling to continue in their present positions, those persons would likely be difficult to replace and our business would likely be harmed. If any of our key employees were to join a competitor or to form a competing company, some of our customers might choose to use the services of that competitor or new company instead of us. Furthermore, customers or other companies seeking to develop in-house capabilities may hire away some of our senior management or key employees. The loss of one or more of these key employees could adversely affect our business.

Envigo must recruit and retain qualified personnel.

Because of the specialized scientific nature of our business, we are highly dependent upon qualified scientific, technical and managerial personnel. There is intense competition for qualified personnel in the biopharmaceutical field. The shortage of qualified scientific, technical and managerial personnel, or other factors, might lead to increased recruiting, relocation and compensation costs for these professionals. These increased costs might reduce our profit margins or make hiring new personnel impracticable. In the future, we may not be able to attract and retain the qualified personnel necessary for the conduct and further development of our business. The loss of the services of existing personnel, as well as the failure to recruit additional key scientific, technical and managerial personnel in a timely manner, could have a material adverse effect on our ability to expand our businesses and remain competitive in the segments in which it participates.

assets, discount rates, participant demographics and changes in pension regulations. Our future costs and funding obligations can increase or decrease significantly depending upon these factors.

Impairment of goodwill or other intangible assets may adversely impact future results of operations.

Envigo has intangible assets, including goodwill on our balance sheet due to acquisitions of businesses. The initial identification and valuation of these intangible assets and the determination of the estimated useful lives at the time of acquisition involve use of management judgment and estimates. The estimates are based on input from accredited valuation consultants and reviews of projected future income cash flows. The use of alternative estimates and assumptions might have increased or decreased the estimated fair value of our intangible assets. If the future growth and operating results of the business are not as strong as anticipated this could impact the assumptions in calculating the fair value of intangible assets. To the extent that intangible assets are impaired, their carrying value will be written down to their implied fair value and a charge made to the income from continuing operations that could materially affect our operating results. During 2020, in large part due to the impact of COVID-19 on our business and results of operations, we recorded an impairment charge of \$39,679, which fully impaired our goodwill. In addition, impairment tests on recoverability triggered by the impact of COVID-19 indicated a partial impairment of our intellectual property resulting in a charge of \$9,827. As of June 30, 2021, the carrying amount of other intangible assets was \$21,087 on our consolidated balance sheets.

The COVID-19 pandemic's impact on global markets could affect our future access to liquidity and materially adversely affect our results of operations and financial condition.

COVID-19 has spread throughout much of the world after initially surfacing in Wuhan, China in December 2019. The future impact of the outbreak of COVID-19 on our business is unknown. Global stock markets, which initially reacted very negatively, have recovered for the most part, but remain subject to volatility due to the continued impact of the pandemic. High unemployment, a partially idled workforce and restrictions on approved activities and travel continue to create economic uncertainty in global markets. While the economic impact brought by COVID-19 continues to be difficult to assess or predict, the COVID-19 pandemic could result in significant disruption of global financial markets, reducing our ability to access capital in the future, which could negatively affect our liquidity in the future. The situation is constantly evolving, however, so the extent to which the COVID-19 outbreak will impact businesses and the economy is highly uncertain and cannot be predicted. Accordingly, we cannot predict the extent to which our results of operations, financial condition and cash flows will be affected.

Envigo is subject to ongoing employment related litigation.

Envigo is the defendant in a class action complaint by a former Envigo employee alleging various California Labor Code violations as well as a count of a violation of the Fair Credit Reporting Act ("FCRA"). The plaintiff's allegations include an alleged failure to pay minimum wage for all hours worked, failure to timely pay wages, failure to reimburse for business expenses, wage statements and recordkeeping violations, and a failure to provide required disclosures pursuant to the FCRA prior to procuring a consumer report or investigate consumer reports. Although this outcome of this complaint is uncertain, it could adversely affect Envigo's financial condition.
